

## **REMARKS**

With entry of this amendment, claims 1-4 are pending. Applicants have canceled withdrawn claims 5-8 without prejudice or disclaimer of the subject matter of these claims. Applicants have amended claim 1 to further clarify the invention. Support for this amendment can be found throughout the specification at, for example, page 2, lines 22-25; page 2, line 31- page 3, line 26; page 4, lines 4-14; and Example 2. Applicants amended claim 4 to correct a grammatical error. Thus, these amendments do not add new matter.

Applicants also amended the specification and the abstract to correct grammatical and typographical errors, as requested by the Office.

The Office rejects claims 1-4 under one or more of 35 U.S.C. §§ 112 and 102. Claim 1 is also objected to for containing a typographical error. Applicants address these objections and rejections below.

### **Claim Objection**

The Office objects to claims 1-4 because claim 1 recites "type-2 astrocytes progenitors." Applicants have amended claim 1 to now recite "type-2 astrocyte progenitors." Because this amendment renders the Office's objection moot, Applicants request that the Office withdraw this objection.

### **Rejection Under 35 U.S.C. § 112**

Claims 1-4 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Office, the term "mainly" in claim 1 is a relative term that is not defined by the claim or the specification. Thus, the Office concludes, the skilled artisan would not be apprised of the scope of claims 1-4.

Solely to facilitate prosecution and without acquiescing in the rejection, Applicants amended claim 1 to remove the disputed term, rendering the Office's rejection moot. Applicants request that the Office withdraw this rejection.

*Rejections Under 35 U.S.C. § 102*

The Office rejects claims 1-4 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent 5,750,376 ("Weiss"). The Office suggests that Weiss teaches generating mixed cultures of O-2A progenitor cells from the spinal cord for transplantation into injured spinal cords to cure a demyelinating lesion. Weiss also allegedly teaches that the glial progenitors are for transplanting into a heterologous, autologous, or xenogeneic host and that the cells are suspended at a density of 50,000 cells/ $\mu$ l. The Office concludes that because these teachings satisfy the elements of claims 1-4, these claims are anticipated. Applicants respectfully traverse.

The Office mis-construes the teaching of Weiss. First, the alleged teachings in Weiss on using O-2A progenitor cells for treating demyelinated lesions do not speak to the composition of claim 1. Myelin is a fatty, insulating material that surrounds the axons of neurons. In demyelinated lesions, these insulating sheaths are destroyed by a disease process, leaving the axons themselves intact. *Arguendo*, even if Weiss's preparation cured a demyelinating disease, this teaches nothing about the preparation's ability to induce regeneration of axons because the axons are intact.

Weiss's apparent discussion of using neural stem progeny on animals with a transected spinal cord (col. 64) does not teach the composition of independent claim 1 either. The use of neuronal stem progeny does not suggest the use of type-2 astrocyte progenitors. Table V in Weiss appears to address the use of neural stem-derived cells

to treat Parkinson's Disease, which is not a model for spinal cord transection. And in Table III, the cells seem to be used on intact spinal cords. Thus, given these two examples of use, Weiss provides no evidence that any beneficial effect that may arise with their treatment was due to the regeneration of axons. Indeed, a later study by Davies et al. (*J. Biol.* 5:7 (2006)) shows that grafting progenitors that are not yet differentiated into astrocyte-lineage cells is not effective at regenerating axons in injured spinal cords.

Finally, the alleged use of O-2A cells by Weiss does not address the element of type-2 astrocyte progenitors recited in claim 1. O-2A progenitor cells and type-2 astrocyte progenitors are two different cell types. See Figure 2B of Ransom, *Ann. N.Y. Acad. of Sci.* 633:19-26 (1991), attached. Rather, O-2A progenitor cells are the precursors of type-2 astrocyte progenitor cells. When O-2A progenitor cells are transplanted into a living body, they develop into oligodendrocytes, not astrocytes. See Espinosa et al., *PNAS-USA* 90:50-54 (1993), attached. Thus, transplantation of neural stem cells or O-2A progenitor cells does not promote differentiation into type-2 astrocyte progenitor cells.

For the reasons enumerated above, Weiss does not teach each and every element of independent claim 1 or dependent claims 2-4. Applicants request that the Office withdraw this rejection.

Claims 1, 3, and 4 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Groves et al., *Nature* 362:453-55 (1993) ("Groves"). According to the Office, Groves teaches generating mixed cultures of rat O-2A progenitor cells and suspending the cells at a density of  $6 \times 10^4$  cells/ $\mu$ l for injection into an injured spinal

cord. Groves also allegedly teaches that the glial progenitors injected into the spinal lesions are allogeneic. The Office then asserts that these teachings anticipate claims 1,3, and 4. Applicants disagree.

Groves appears to discuss a study in which purified O-2A progenitor cells were used to treat demyelinated lesions. As discussed above with Weiss, treating demyelination has nothing to do with regenerating axons. They are different phenomena. In a demyelinated lesion, the myelin sheath is damaged, but the axons themselves are left intact. In contrast, to achieve the invention's success of rehabilitating a transected spinal cord, both axonal rehabilitation and myelin rehabilitation are required because a complete transection damages both the myelin sheath and the axons themselves. Examples 2-4 in the specification clearly show that the therapeutic composition of the invention restored both myelin and axon function, as evidenced by the ability of the test animals to walk.

In addition, as discussed above, the use of O-2A progenitor cells in Groves does not address the use of glial cells including cultured type-2 astrocyte progenitors as recited in claim 1. O-2A progenitor cells and type-2 astrocyte progenitor cells are different cell types.

Because Groves does not teach every element of independent claim 1 and dependent claims 3 and 4, Applicants request that the Office withdraw this rejection.

#### Conclusions

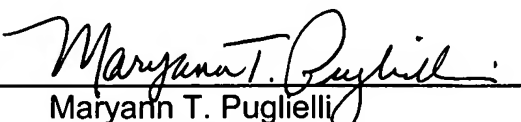
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of pending claims 1-4.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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**Attachments:** Replacement abstract; Davies et al. (*J. Biol.* 5:7 (2006); Ransom, *Ann. N.Y. Acad. of Sci.* 633:19-26 (1991); and Espinosa et al., *PNAS-USA* 90:50-54 (1993).